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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,597	04/30/2001	Antoni P. Tomsia	IB-1627	3236

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LAWRENCE BERKELEY NATIONAL LABORATORY
ONE CYCLOTRON ROAD, MAIL STOP 90B
UNIVERSITY OF CALIFORNIA
BERKELEY, CA 94720

EXAMINER

SPERTY, ARDEN B

ART UNIT PAPER NUMBER

1775

DATE MAILED: 09/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/845,597

Applicant(s)

TOMSIA ET AL.

Examiner

Arden B. Sperty

Art Unit

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,8,12 and 20-30 is/are pending in the application.
- 4a) Of the above claim(s) 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,8,12,20-28 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

FIRST OFFICE ACTION FOLLOWING RCE

1. Claims 1, 3, 5, 8-12, and 20-30 are pending.

Election/Restrictions

2. Newly submitted claim 29 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The claim is drawn to a patentably distinct species wherein the SiO₂ concentration gradient is formed by a first layer, which is farthest away from the substrate, having the highest SiO₂ concentration, while a second intermediate layer, which is closest to the substrate, has the lowest SiO₂ concentration. A search of the prior art has not been performed for this patentably distinct species.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 29 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Priority

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 111(b)(1) as follows:

Section 35 USC 111(b)(1) states:

Such application shall include- (A) a specification as prescribed by the first paragraph of section 112 of this title.
The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Applicant's claim for priority to Provisional Application 60/201,556 is denied because the provisional application merely contains a collection of articles which is not seen to constitute a written description of this invention, and of the manner and process of making and using it, in such *full, clear, concise, and exact terms* (emphasis added) as is required by 35 USC 111(b)(1).

Information Disclosure Statement

4. It should be noted that the IDS designates three articles as Prior Art which are also included as part of the "Provisional Application."

Specification

5. The amendment filed September 9, 2003, is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: a multilayer article wherein the SiO₂ concentration gradient is formed by a first layer, which is farthest away from the substrate, having the highest SiO₂ concentration, while a second intermediate layer, which is closest to the substrate, has the lowest SiO₂ concentration.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 25 and 27 recite a range with an upper limit of "about 68 wt%". There is insufficient antecedent basis for this limitation in the claims. The specification specifically says on page 7, line 12 that "about" allows for +/- 0.1, wt %. The range of claim 1 has an upper limit of 67.7 wt %, which does not equal 68 wt% +/- 0.1 wt%.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 8 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by the article titled "HA-bioactive glass composites: High temperature reactivity and 'in-vitro' behavior" by Pazo, et al.

Regarding claim 1, the reference teaches a multilayered article (see text of page 1733 and Figures 6 and 7) comprising a Ti or Ti alloy substrate (see line 6 of abstract) and a first layer comprising a glass of the claimed composition (see page 1729, first paragraph under "Materials and Methods), further comprising HA in an amount of 25% (up to 50%) (page 1729, last paragraph).

Regarding claim 8, the substrate is Ti or Ti alloy (abstract line 6).

Regarding claim 23, the reference teaches the amount of SiO₂ within the claimed range (page 1729, first paragraph under “Materials and Methods”).

10. Claims 1, 8 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by “Silicate glass coatings on Ti-based implants,” by Pazo, et al.

Regarding claim 1, the reference teaches a multilayer article (see page 2553, right column, lines 8-10) comprising a metal substrate (page 2551, left column, lines 2-3), and a first layer comprising the claimed glass composition (Table 1, samples A-3 and A-5).

Regarding claim 8, the substrate is Ti or Ti alloy (page 2551, left column, lines 2-3), specifically Ti-6Al-4V (page 2553, right column, bottom of first full paragraph).

Regarding claim 23, the reference teaches an amount of SiO₂ within the claimed range (Table 1, samples A-3 and A-5).

11. Claims 1, 3, 5, 8-12, and 20-28 are rejected under 35 U.S.C. 102(b) as being anticipated by “Glass-hydroxyapatite coatings on titanium-based implants” by Gomez-Vega et al, published February 2000.

Regarding claim 1, the reference teaches a multilayer article (see bottom of page 16) comprising a metal substrate (see abstract), and a first layer comprising the claimed glass composition (Table I, samples 6P55, 6P57, 6P61) and an amount of HA within the claimed range (bottom of page 16).

Regarding claim 3, the reference teaches the article of claim 1 having multiple layers (intermediate layers) (page 19, lines 1-8) comprising a glass composition as defined in claim 1 (see Table I).

Regarding claim 5, the reference teaches the article of claim 3 having a first intermediate layer having a HA concentration of 0%, a second intermediate layer having a HA concentration of 20%, and a first layer having a HA concentration of 40% (page 19, lines 1-8).

Regarding claim 8, the reference teaches the article of claim 1 wherein the substrate is Ti-6Al-4V (see abstract).

Regarding claims 9-12, the reference teaches the claimed glass compositions on a substrate of Ti-6Al-4V and HA concentrations meeting the claim limitations (Table I and bottom of page 16).

Regarding claim 20, the reference discloses a multilayer article comprising a Ti6Al4V substrate (see abstract) having a first layer and 2 intermediate layers, the layers comprising the claimed glass composition (see Table I) and an amount of HA within the claimed range (bottom of page 16).

Regarding claims 21 and 23, Table I shows the SiO₂ content of samples 6P55 and 6P57 to be within the claimed range.

Regarding claims 22 and 24, the bottom of page 16 teaches $n=2$.

Regarding claims 25 and 27, Table I shows the SiO₂ content of sample 6P61 to be within the claimed range.

Regarding claims 26 and 28, the bottom of page 16 teaches $n=2$.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over “Glass-hydroxyapatite coatings on titanium-based implants” by Gomez-Vega et al, published February 2000 as applied above, and further in view of “A multilayer approach to fabricate bioactive glass coatings on Ti alloys,” by Gomez-Vega et al, published 1999.

While the 2000 Gomez-Vega reference discloses a multilayer article as presently claimed wherein $n=2$ (having a second intermediate layer between the first intermediate layer and the substrate), the reference is silent with respect to a SiO_2 gradient wherein the highest SiO_2 concentration is closest to the substrate. The reference further states that a desired quality in the multilayer article was good adhesion of the coatings to metal (Introduction, the paragraph that spans the bottom of page 15 to the top of page 16). The 1999 Gomez-Vega reference teaches a multilayer article having a metal substrate, glass layers having the claimed composition, and an outer layer having HA particles embedded therein, further having an SiO_2 gradient wherein the highest SiO_2 concentration is closest to the substrate to achieve excellent adhesion to the metal substrate. Therefore, since excellent adhesion to the substrate is a desirable quality in the multilayer article of the 2000 Gomez-Vega reference, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the multilayer article

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having an HA gradient according to the 2000 Gomez-Vega reference with the 1999 Gomez-Vega reference to achieve excellent adhesion to the metal substrate.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arden B. Sperty whose telephone number is 703-305-3143. The examiner can normally be reached on M-R, 08:00-16:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Jones can be reached on 703-308-3822. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.


Arden B. Sperty
Examiner
Art Unit 1775


DEBORAH JONES
SUPERVISORY PATENT EXAMINER